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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,863	11/19/1999	INDU PARIKH	401930/SKYE PHARMA	7862

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/06/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/443,863

Applicant(s)  
Parikh

Examiner  
Gollamudi Kishore, Ph.D

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 1, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 50-96 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 30 6) ☐ Other:

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### **DETAILED ACTION**

**The request for the extension of time and filing under 1.114 dated 5-23-03, the amendment dated 7-11-03 are acknowledged.**

**Claims included in the prosecution are 50-96.**

#### ***Claim Rejections - 35 USC § 102***

**1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless -**

**(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**

**2. Claims 50-96 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/07414 of record.**

**WO discloses the same process of preparation for the rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with at least two surfactants; one of the surfactants is a phospholipid (surface modifying agent). The average particle sizes of the hydrophobic compound is less than 10 microns. The composition contains other claimed materials such as celluloses and mannitol. The process of preparation involves the mixing of the components and lyophilizing the composition to form particles (note the abstract, page 2, line 25 through page 8, line 19, Examples and claims).**

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***Claim Rejections - 35 USC § 103***

**3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

**4. Claims 50-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarwood (5,827,541) by itself or in further combination with Green (5,976,577) of record or Na (5,326,552) also of record.**

**Yarwood discloses a process for the rapidly dispersing oral dosage forms of hydrophobic compounds wherein the particles are coated with a surfactant (surface modifying agent). The average particle sizes of the hydrophobic compound is less than 10 microns. The composition contains other materials such as celluloses and mannitol. The process of preparation involves the mixing of the components and lyophilizing the composition to form particles. (note the abstract, column 1, line 54 through col. 4, line 14, Examples and claims). What is not disclosed in Green is the range of claimed sizes. Yarwood does not disclose phospholipids as the surfactant; Yarwood also does not teach a combination of surfactants. However, it should be pointed out that according to Yarwood on col. 2, line 51 et seq., any surfactant which fulfills the requirement of pharmaceutical acceptability may be used. Therefore, it would have been obvious to one of ordinary skill in the art to use phospholipids which are well know surfactants in the process of Yarwood based on this suggestion and from the guidance provided with a reasonable expectation of success. One of ordinary skill in the art would be further motivated to use phospholipids**

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with the expectation of obtaining at least similar results, in view of the references of Green, and Na both of which teach the use of phospholipids to coat sub-micron size particles just as in instant method (see abstract and col. 5, lines 30-48 of Green; abstract, col. 2, lines 49-53; col. 3, line 65 through col. 4, line 38).

**NOTE:** the references cited on 1449 have not been considered since applicant has not stated their relevancy; applicant has also not provided copies of the references.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility

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**that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**October 3, 2003**